Supplement to

INFORMATION LETTER

NATIONAL CANNERS ASSOCIATION

No. 1765 Washington, D. C. February 6, 1960

FDA REGULATION UNDER FOOD ADDITIVE LAW

(from Federal Register of Feb. 2, 1960)

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart E—Substances for Which Prior Sanctions Have Been Granted

SUBSTANCES EMPLOYED IN THE MANUFACTURE OF FOOD-PACKAGING MATERIALS

In accordance with the provisions of section 701(a) of the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055; 21 U.S.C. 371(a) and pursuant to authority delegated to him by the Secretary of Health, Education, and Welfare (23 F.R. 9500), the Commissioner of Food and Drugs, as contemplated by sections 201(s)(3) and 409 of the act (secs. 201(s), 409, 72 Stat. 1784 et seq.; 21 U.S.C. 321, 348) and the regulations thereunder (§ 121.3(c) (24 F.R. 2435)), has compiled a list of substances in the above-identified category for which prior sanction or approval has been granted. *It is ordered*, That the food additives regulations be amended by adding thereto a list of these substances as set out below:

Subpart E—Substances for Which Prior Sanctions Have Been Granted

§ 121.2001 Substances employed in the manufacture of food-packaging materials.

Prior to the enactment of the food additives amendment to the Federal Food, Drug, and Cosmetic Act, sanctions were granted for the usage of the following substances in the manufacture of packaging materials. So used, these substances are not considered "food additives" within the meaning of section 201(s) of the act, provided that they are of good commercial grade, are suitable for association with food, and are used in accordance with good manufacturing practice. For the purpose of this section, good manufacturing practice for food-packaging materials includes the restriction that the quantity of any of these substances which becomes a component of food as a result of use in food-packaging materials shall not be intended to accomplish any physical or technical effect in the food itself, shall be reduced to the least amount reasonably possible, and shall not exceed any limit specified herein.

(a) *Antioxidants (limit of addition to food, 0.005 percent).*
- Butylated hydroxyanisole.
- Butylated hydroxytoluene.
- Dilauryl thiodipropionate.
- Distearyl thiodipropionate.
- Gum guaiac.
- Nordihydroguairetic acid.
- Propyl gallate.
- Thiodipropionic acid.
- 2,4,5-Trihydroxy butyrophenone.

(b) *Antimycotics.*
- Calcium propionate.
- Methylparaben (methyl p-hydroxybenzoate).
- Propylparaben (propyl p-hydroxybenzoate).
- Sodium benzoate.
- Sodium propionate.
- Sorbic acid.

(c) *Driers.*
- Cobalt caprylate.
- Cobalt linoleate.
- Cobalt naphthenate.
- Cobalt tallate.
- Iron caprylate.
- Iron linoleate.
- Iron naphthenate.
- Iron tallate.
- Manganese caprylate.
- Manganese linoleate.
- Manganese naphthenate.
- Manganese tallate.

(d) *Drying oils (as components of finished resins).*
- Chinawood oil (tung oil).
- Dehydrated castor oil.
- Linseed oil.
- Tall oil.

(e) *Plasticizers.*
- Acetyl tributyl citrate.
- Acetyl triethyl citrate.
- p-*tert*-Butylphenyl salicylate.
- Butyl stearate.
- Butylphthalyl butyl glycolate.
- Dibutyl sebacate.
- Diethyl phthalate.
- Diisobutyl adipate.
- Diisooctyl phthalate (for foods of high water content only).
- Diphenyl-2-ethylhexyl phosphate.
- di-(2-Ethylhexyl) phthalate (for foods of high water content only).
- Epoxidized soybean oil (iodine number maximum 6; and oxirane oxygen, minimum, 6.0 percent).
- Ethylphthalyl ethyl glycolate.
- Glycerol monooleate.
- Monoisopropyl citrate.
- Mono, di-, and tristearyl citrate.
- Triacetin (glycerol triacetate).
- Triethyl citrate.
- 3-(2-Xenoyl)-1,2-epoxypropane.

(f) *Release agents.*
- Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups, no more than 18 percent loss in weight after heating 4 hours at 200° C.; viscosity 300 centistokes, 600 centistokes at 25° C., specific gravity 0.96 to 0.97 at 25° C., refractive index 1.400 to 1.404 at 25° C.)
- Linoleamide (linoleic acid amide).
- Oleamide (oleic acid amide).
- Palmitamide (palmitic acid amide).
- Polyethylene glycol 400.
- Polyethylene glycol 1500.
- Polyethylene glycol 4000
- Stearamide (stearic acid amide).

(g) *Stabilizers.*
- Aluminum mono-, di-, and tristearate.
- Ammonium citrate.
- Ammonium potassium hydrogen phosphate.
- Calcium acetate.
- Calcium carbonate.
- Calcium glycerophospate.
- Calcium phosphate.
- Calcium hydrogen phosphate.
- Calcium oleate.
- Calcium ricinoleate.
- Calcium stearate.
- Disodium hydrogen phosphate.
- Magnesium glycerophosphate.
- Magnesium stearate.
- Magnesium phosphate.
- Magnesium hydrogen phosphate.
- Mono-, di-, and trisodium citrate.
- Mono-, di-, and tripotassium citrate.
- Potassium oleate.
- Potassium stearate.
- Sodium pyrophosphate.
- Sodium stearate.
- Sodium tetrapyrophosphate.

Tin stearate (not to exceed 50 parts per million tin as a migrant in finished food).

Zinc orthophosphate (not to exceed 50 parts per million zinc as a migrant in finished food).

Zinc resinate (not to exceed 50 parts per million zinc as a migrant in finished food).

Notice and public procedure are not necessary prerequisites to the promulga-

tion of this order since the listing of the substances herein implements the regulation (§ 121.3) previously promulgated, since it relieves the Food and Drug Administration from the necessity of advising of individual sanctions upon request of the affected industry, and since it relieves the industry from the necessity of requesting advice concerning the use of substances for which sanctions have already been granted.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER, since interested persons will benefit by the earliest effective date, and I so find.

(Sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 371. Interprets or applies secs. 201(s), 409, 72 Stat. 1784 et seq., 21 U.S.C. 321(s), 348)

Dated: January 26, 1960.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

Product [1]	Limits	Conditions
CHEMICAL PRESERVATIVES		
Calcium sorbate		
Methylparaben (methyl-*p*-hydroxybenzoate).	0.1 percent	
Propylparaben (propyl-*p*-hydroxybenzoate).	0.1 percent	
Stannous chloride	0.0015 percent, calculated as tin	
BUFFERS AND NEUTRALIZING AGENTS		
Adipic acid		
Hydrochloric acid		
Malic acid		
Phosphoric acid		
Succinic acid		
NONNUTRITIVE SWEETENERS		
Ammonium saccharin		
Magnesium cyclohexyl sulfamate		
Potassium cyclohexyl sulfamate		
NUTRIENTS		
Choline bitartrate		Animal feeds.
Glycine (aminoacetic acid)		
Inositol		
Methionine	0.0125 percent	Do.
Methionine hydroxy analog and its salts.	0.0125 percent	Do.
STABILIZERS		
Acacia (gum Arabic)		
Ammonium alginate		
Calcium alginate		
Ghatti gum		
Potassium alginate		
Sodium alginate		
Sterculia gum (karaya gum)		
Tragacanth (gum tragacanth)		
ANTICAKING AGENTS		
Sodium aluminosilicate	2 percent	
Sodium calcium aluminosilicate, hydrated.	2 percent	
MISCELLANEOUS		
Ammonium bicarbonate		
Ammonium sulfate		
Beeswax (yellow wax)		
Beeswax, bleached (white wax)		
Bentonite		
Calcium chloride		
Dextrans (of average molecular weight below 100,000).		
Glutamic acid		Salt substitute.
Glutamic acid hydrochloride		Salt substitute.
Hydrogen peroxide		Bleaching agent.
Lecithin		
Mannitol	5 percent	In special dietary foods.
Methylcellulose (U.S.P. methylcellulose, except that the methoxy content shall not be less than 27.5 percent and not more than 31.5 percent on a dry-weight basis).		
Monopotassium glutamate		
Nitrous oxide		Propellant for certain dairy and vegetable fat toppings in pressurized containers.
Potassium carbonate		
Potassium sulfate		
Rennet (rennin)		
Silica aerogel (finely powdered microcellular silica foam having a minimum silica content of 89.5 percent).	0.00005 percent	Component of antifoaming agent.
Sodium bicarbonate		
Sodium carboxymethylcellulose (the sodium salt of carboxymethylcellulose, not less than 99.5 percent on a dry-weight basis, with maximum substitution of 0.95 carboxymethyl groups per anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2 percent by weight aqueous solution at 25° C.).		
Sodium caseinate		
Sodium sesquicarbonate		
Sodium pectinate		
Torula yeast, dried		

[1] All items listed should, of course, comply with the conditions prescribed in (§ 121.101 (a) and (b). With reference to the inclusion of items listed as nutrients, see (§ 121.101 (c).

[1] This list supplements the list published in the FEDERAL REGISTER of November 20, 1959 (24 F.R. 9369).

Dated: January 26, 1960.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

FOOD ADDITIVES

Substances Generally Recognized as Safe; Supplementary List

The Commissioner of Food and Drugs, on his own initiative, and in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 409, 701; 72 Stat. 1785 et seq.; 52 Stat. 1055, as amended 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 348, 371) and pursuant to the authority delegated to him by the Secretary of Health, Education, and Welfare (23 F.R. 9500), proposes the promulgation of a regulation listing certain substances generally recognized as safe within the meaning of section 409 of the act,[1] and hereby offers an opportunity to all interested persons to present their views in writing with reference to this proposal to the Hearing Clerk, Department of Health, Education, and Welfare, 330 Independence Avenue SW., Washington 25, D.C., within 30 days from the date of publication of this notice in the FEDERAL REGISTER. Comments may be accompanied by a memorandum or brief, and it is requested that all comments be submitted in quintuplicate.